



Association for Molecular Pathology
Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology

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Divided Appeals Court Rules on BRCA Case

In a 2-1 decision, a federal appeals court today partially reversed a lower court's ruling in AMP's case that challenges patents on two human genes associated with hereditary breast and ovarian cancer.

FOR IMMEDIATE RELEASE

July 29, 2011

BETHESDA – In a 2-1 decision, a federal appeals court today partially reversed a lower court's ruling in a case challenging patents on two human genes, BRCA1 and BRCA2, associated with hereditary breast and ovarian cancer. The court ruled that companies can obtain patents on the genes but cannot patent methods to compare those gene sequences.

The lawsuit, *Association for Molecular Pathology, et al. v. Myriad Genetics, Inc.*, charged that the challenged patents are illegal and restrict both scientific research and patients' access to medical care, and that patents on human genes violate the First Amendment and patent law because genes are "products of nature."

"AMP's position agrees with the dissent from today's decision. Genes or a sequence of the genome is a product of nature and should not be patentable," said Timothy J. O'Leary, MD, PhD, AMP President. "While attaching intellectual property rights to true acts of invention such as new therapeutics, diagnostics, or technology platforms is essential to encourage investment and reward innovation, gene patents can serve as a disincentive to innovation in molecular testing because they deny access to a vital baseline of genomic information that cannot be invented around."

One of the three judges on the panel dissented in part with the decision, writing that patents on the genes should be invalid. "...[E]xtracting a gene is akin to snapping a leaf from a tree," Judge William C. Bryson of the U.S. Court of Appeals for the Federal Circuit wrote. "Like a gene, a leaf has a natural starting and stopping point. It buds during spring from the same place that it breaks off and falls during autumn. Yet prematurely plucking the leaf would not turn it into a human-made invention."

The lawsuit was filed by the American Civil Liberties Union (ACLU) and the Public Patent Foundation (PUBPAT) on behalf of breast cancer and women's health groups, individual women, geneticists and scientific associations representing approximately 150,000 researchers, pathologists and laboratory professionals. Because the ACLU's lawsuit challenges the whole notion of gene patenting, its outcome is likely to have far-reaching effects beyond the patents on the BRCA genes.

Dr. O'Leary continued, "Gene patents and exclusive licenses that confine molecular testing to a single provider are detrimental to the public interest by limiting patient access to testing. Monopolies on gene testing make it impossible for patients to access alternate tests or get a second opinion about their results. AMP will continue to advocate until a resolution is found either in the courts or in legislation."

Today's decision can be found online at: http://www.amp.org/documents/CAFCRulingBRCA_Jul29_2011.pdf

AMP's Position on Gene Patents and Exclusive Licensing can be found online at:

http://www.amp.org/publications_resources/position_statements_letters/Gov/GenePatentPositionStatement_Final_Nov2008.pdf.

About AMP:

The Association for Molecular Pathology (AMP) is an international medical professional association dedicated to the advancement, practice, and science of clinical molecular laboratory medicine and translational research based on the applications of molecular biology, genetics, and genomics. For more information, please visit www.amp.org.

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